

Remote Qualification Questionnaire

1.0 Introduction and Completion Instructions

PURPOSE:

Completion of this form by a vendor allows for PRA to perform a remote qualification (for new vendors or part of a periodic assessment for previously qualified vendors).

USE:

Following completion of this questionnaire, PRA will review the information to determine whether remote qualification (pending further information/interviews, as applicable) can be completed or if an audit (remote or on-site) is needed. This questionnaire will be made available to PRA personnel who are involved in evaluating your company or who otherwise have a need to know such information. An audit certificate documenting the outcome of the review of this questionnaire may be provided to PRA clients upon request.

COMPLETION INSTRUCTIONS:

Please distribute the attached questionnaire amongst the most relevant persons within your company for completion. Attachments can be provided either embedded into the questionnaire, as a separate zip folder or in any other manner which is acceptable to your company. Note that not all the questions may apply to your company so do not hesitate to mark "N/A or not applicable" if you feel the question is not relevant/applicable. If you mark a question as N/A or are not able to provide the requested documented as attachments, please add text to explain the rationale.

If this is the first time you have received a questionnaire from PRA QA to complete:

We would encourage you to respond to all questions included in each section and provide all the requested attachments.

If this is not the first time you are receiving a questionnaire from PRA QA (e.g. **for requalification purposes**):

If no significant changes have occurred since the last qualification questionnaire was completed, please tick the box as indicated at the beginning of the section. Otherwise, please complete the questions within the section and provide the requested attachments.

Vendor Information	
Vendor Name	Cogstate Inc.
Contact Name and Title:	Lammert Albers, Chief Commercial Officer
Address:	195 Church Street, 4 th Floor, New Haven, CT 06510 USA; 1350 Broadway, Suite 1620, New York, NY 10018 USA; 255 Bourke Street, Level 2 Melbourne VIC 3000 Australia
Phone:	+1 203 773 5010
Email:	lalbers@cogstate.com
Company website address	https://www.cogstate.com
Date of Assessment: (Sent to Vendor)	22-May-2019

2.0 Company Overview

For requalification only:

If no changes have occurred since the last PRA QA qualification questionnaire, please check this box ☐

- Please provide the rationale if no changes applicable to the ENTIRE section:
- Otherwise please complete all questions in the table below and provide the requested attachments

Questions	Responses
Please provide an organizational chart as an attachment to the questionnaire	
<p>If organizational chart cannot be provided explain the reason and alternatively describe the company structure: An org chart has been provided within the Due Diligence Questionnaire (DDQ). Please verify if the document here attached is still applicable or a new one should be provided.</p> <p>Please refer to Cogstate Org Charts_28 May 2019.pdf, provided with this submission.</p>	
How many years has the company been in business?	20 years
How many years has the company operated under the current management team?	Cogstate has operated under the leadership of CEO, Brad O'Connor, for over 15 years, and the average tenure of the senior leadership team is 9 years.
Provide the number of employees across the organization	140 Full Time 5 Part-Time 116 Contractors, including our Global LEAD network
Is the company currently or recently in negotiations to be acquired or to acquire or partnership with another company?	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>If YES to the question above, please provide details: Cogstate has no publicly announced plans for acquisition.</p>	
Does the company sub-contract any services?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<p>If YES to the question above, provide information regarding for which services: • Harte Hanks – Logistics Provided for Shipping/Inventory of Hardware outside of United States • Transperfect – Translation Vendor • Lionbridge – Translations • Mapi - Translations • Mimeo – Printing/Distribution • Clinical Ink-eCOA services • RWS - translations • Ce3 – statistical analysis services • Metrum Research Group – statistical analysis services</p>	
Is there a process/SOP in place describing how clients confidential information is maintained within your Global network of clinicians/neuropsychologists for rater performance?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<p>If YES, please describe: Each Local Expert Advisor (LEAD) in our global network completes General Data Protection Regulation (GDPR) training on an annual basis. In addition, some studies pose specific Protected Health Information (PHI) requirements, to which Cogstate trains LEADs during study start-up.</p>	
Does the company perform any customer satisfaction surveys?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Does the company host client audits?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Has the company been inspected by a regulatory agency?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

If YES to the above question, provide details (inspection body, dates, outcome, as applicable):

Provide a brief description of the services offered by your company; provide a **company brochure / presentation**, if available

Cogstate's Clinical Trials solutions are organized into two core areas:

Computerized Cognitive Assessment

Rapid, Sensitive and Reliable Tests Designed for Clinical Research

- Screening, inclusion/exclusion criteria, safety and efficacy endpoints
- Computerized cognitive tests increase the sensitivity and specificity of the measurement of human cognitive processes
- Designed, developed and validated to withstand the numerous operational challenges of conducting clinical trials, such as:
 - testing patient groups with unique characteristics
 - working with sites in countries or cultures with limited experience with cognitive testing
 - protocol schedules where there is often limited time available for assessment

eCOA, Rater Training & Central Monitoring

Reducing Trial Risk by Ensuring Higher Quality Outcome Measures

- Scientific and operational expertise in cognitive and behavioral scales:
 - Scales selection/consultation and management (permissions and licenses, source docs, translations, logistics)
 - Rater training and training materials development (didactic slides, videos, quizzes, scoring exercises, audio/video recorded practice, etc.)
 - Central monitoring (forms, data-based, audio, video)
- Enhanced tablet-based eSource data capture for eCOA
- Global capabilities and extensive network of expert consultants in over 30 countries

For more details, please see these materials overviewing our capabilities: <https://bit.ly/2wSMEfJ>

Provide a list of the locations that would support PRA contracted services:

195 Church Street, 4th Floor, New Haven, CT 06510 USA; 1350 Broadway, Suite 1620, New York, NY 10018 USA; 255 Bourke Street, Level 2 Melbourne VIC 3000 Australia

Provide an overview of the physical security of the locations:

Access is controlled with a swipe card. There is a receptionist as well. The lobby of the building has a security guard. All employees are responsible for maintaining the physical security of Cogstate's offices. It is stated in our employee handbook, that "Employees should participate in, and comply with the directives of, the Company's security awareness training and otherwise develop habits that ensure security as a matter of course."

Provide **SOPs / written procedures** related to physical security
(SOP IT 003: Security Controls)

For US Companies Only:

For requalification only:

If no changes have occurred since the last PRA QA qualification questionnaire, please check this box ☐

- Please provide the rationale if no changes applicable to the ENTIRE section:

- Otherwise please complete all questions in the table below and provide the requested attachments

Questions	Responses	
Is your company a small business concern as defined by FDA 13 CFR Part 121?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

Is your company a small disadvantaged business concerns as defined by FDA 13 CFR Part 124.1002?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
If YES, check which category:	<input type="checkbox"/> small disadvantaged business (51% owned or controlled by at least one disadvantaged person (socially, economically, including ANCs and Indian Tribes) <input type="checkbox"/> woman-owned small business <input type="checkbox"/> historically underutilized business zone small business <input type="checkbox"/> veteran-owned small business and service-disabled veteran-owned small business	

3.0 Data Protection, Personally Identifiable Information (PII), and Corporate Compliance

For requalification only:

If no changes have occurred since the last PRA QA qualification questionnaire, please check this box ☐

- Please provide the rational if no changes applicable to the ENTIRE section:
- Otherwise please complete all questions in the table below and provide the requested attachments

Questions	Responses	
Will your company be collecting, processing and storing Personally Identifiable Information (PII) in providing the services to customer (i.e., personal information that alone or in combination with other information may enable a 3 rd party to determine the identity of an individual)?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Will your company be transferring Personally Identifiable Information (PII) across international boundaries?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Is there a mechanism in place for international data transfer such as Binding Corporate Rules, Model contracts, etc.?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
If YES answered to the above question, specify: Model clauses		
Will customers Personally Identifiable Information (PII) be disclosed to third parties?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
If YES answered to the above question, specify purpose: Yes to third parties for provision of the services in accordance with the study protocol / customer agreement.		
Does your company have policies relevant to:		
• Code of Ethics?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
• Anti-bribery / anticorruption?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
• Data Privacy?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
If one of the above is answered NO, please explain the rational.		
If one or more of the above is answered YES, please provide a copy of the applicable Policies		
Do you have the following designated employees (or equivalents):		
• Data Privacy Officer?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
• Corporate Compliance Officer?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No

• Information Security Officer?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Does your company include, as part of routine monitoring/audits both internally and of subcontracted services, the following compliance checks?		
• Data Privacy	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
• Anti-Corruption	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
• Information Security	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Does your Ethics Code, Information Security or Anti-Corruption program extend to sub-contractors performing outsourced services?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> N/A
If N/A, please explain the reason:		
Do you have systems/controls in place for the secure storage of sponsor information that maintains confidentiality?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> N/A
If N/A, please explain the reason:		
If YES to the above question, provide details of the systems and controls that are in place: Details of systems and controls are covered by Cogstate's overall data privacy and security compliance program.		
Provide SOPs / Policies / written procedures related to the systems and controls that are in place (SOP IT 003: Security Controls, SOP IT 013: Maintenance and Control of the IT Infrastructure, SOP HIP 01: HIPAA & GDPR Compliance, SOP HIP 02: Cogstate Information Security Program, SOP HIP 03: Acceptable Uses and Disclosures PHI & Processing of Personal Data, SOP HIP 04: Patient Access PHI and Data Subject Rights, SOP HIP 06: Acceptable Use Policy, SOP HIP 07: Facility Access Policy, SOP HIP 08: Information Systems Risk Management, SOP HIP 09: Network System Security Measures, SOP HIP 10: Security Incident Response Plan, SOP HIP 11: Sanctions Enforcement Policy, SOP HIP 12: Identification Authentication, SOP HIP 13: Encryption Policy)		

4.0 Quality Management System

For requalification only:	
If no changes have occurred since the last PRA QA qualification questionnaire, please check this box <input type="checkbox"/>	
<ul style="list-style-type: none"> Please provide the rational if no changes applicable to the ENTIRE section: Otherwise please complete all questions in the table below and provide the requested attachments 	
Questions	Responses
Is your quality system accredited or certified?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
If YES to the question above, please attach a copy of the certification / accreditation	
Does the company operate in accordance with any national or global regulatory requirements?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
If YES, please list which regulations the company operate if accordance with (e.g. GCP, GMP, GLP, local / national regulations, etc.): GCP, ICH E6 (R2), and CFR Part 11 requirements.	
Is a Policy / SOP Index available?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

<p>If YES, please attach a copy of the Policy / SOP index (English version, if possible) Please verify if the list attached it is still applicable or a new one should be provided.</p> <p>Please refer to Cogstate SOP List_11 Jun 2019.pdf, provided with this submission.</p>		
Is there a QMS manual/Site Master File(s) available?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
<p>If YES, please attach a copy of the QMS Manual /Site Master File(s) as applicable (English version, if possible) (Please note that per Cogstate's policy, copies of procedures and policies can be provided for viewing via Virtual Room and not via emails)</p>		
Does the Company use Global or Local SOPs?	<input checked="" type="checkbox"/> Global	<input type="checkbox"/> Local
Are SOPs available in English?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Are Standard Operating Procedures (SOPs) or other policies and procedures readily available to all personnel?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
<p>Briefly describe how SOPs are readily available and how staff are informed of updated SOPs: SOPs are readily available to all staff through Cogstate's secure Box QA folder maintained by Quality Assurance. Cogstate staff are notified of new or updated SOPs by a member of the Quality Assurance department via email when they are effective.</p>		
<p>Are there documented policies and/or procedures in place for the following:</p> <ul style="list-style-type: none"> Misconduct and/or Suspected Fraud Privacy Breach Management (which includes customer notification) Management of received Unrequested Personally Identifiable Information (PII) Retention Policy (of data types that require governance & oversight) Issue Escalation/Customer Complaints CAPA and/or Process Deviation Program Anti- Human Trafficking/Slavery Vendor / Supplier Management Project Management Contract Management 	<input checked="" type="checkbox"/> Yes <input checked="" type="checkbox"/> Yes <input checked="" type="checkbox"/> Yes <input checked="" type="checkbox"/> Yes <input checked="" type="checkbox"/> Yes <input checked="" type="checkbox"/> Yes <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Yes <input checked="" type="checkbox"/> Yes <input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input checked="" type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No
<p>Provide the documented policies and/or procedures for each of the above available processes If no written procedures in place, please describe the processes the company implements to manage the above listed areas: Anti-Human Trafficking/Slavery – Cogstate's Code of Conduct and Employee Handbook require that all employees act ethically, responsibly and in accordance with all applicable laws, rules and regulations. If any vendor, contractor or other supplier is suspected of being involved in prohibited activity or suspected of involvement, the employee that discovers the involvement or suspected involvement will report it to their supervisor or the Cogstate Legal group.</p>		
<p>Does your company maintain for all staff:</p> <ul style="list-style-type: none"> CVs Job descriptions 	<input checked="" type="checkbox"/> Yes <input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> No
Is there new employee training available for different roles within the company?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Does the company require training on applicable regulations?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Are training records maintained for all employees, including contract or part-time employees?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Does training include testing or other documented assessment of comprehension?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No

Provide a brief description of the training program in place, including training on SOPs, regulations and other courses:

Training Needs Guideline (TNG) is developed based on each job title, which includes training on SOPs and applicable regulations as well as competency training. Annual training requirement is also defined in TNG. Our Training and Development process for employees is detailed in our SOP ADM 002: Training and Development.

Cogstate training program uses a variety of training modalities including instructor-led training, online training, hands-on learning, blended learning, and train the trainer. Training assignment and completion is managed and tracked through our Learning Management System (LMS), Cleo.

Provide **SOPs / written procedures** related to training of staff
(SOP ADM 002 Training and Development)

Describe the process for issue escalation and how customer complaints are handled:

Cogstate operational team is responsible for escalating customer related issues to Quality Assurance (QA) since they are the main contact for study sites. Customer complaints are handled per SOP ADM 008: CAPA, Deviations and Non-Conformances. The study Project Manager will initiate the CAPA or coordinate with QA to initiate the CAPA. The CAPA is then assigned to the responsible division for root cause analysis and action plans. The QA and Operations department heads discuss complaints and CAPAs during management meetings.

Provide a brief explanation of the CAPA process (including identification, follow up until closure, and how customer is kept informed):

Customer complaints are handled per SOP ADM 008: CAPA, Deviations and Non-Conformances. Cogstate operational team is responsible for escalating customer related issues to Quality Assurance (QA) since they are the main contact for study sites. Cogstate uses a tiered CAPA system. The CAPA report is used to document root cause analysis and corrective/preventive action(s) for major non-conformances. The non-conformance report is used to document root cause analysis and corrective action(s) for minor non-conformances/observations. The sponsor will be notified if the issue affects sponsor data. JIRA tracking system is used to log and track the issue until closure. QA will perform effectiveness monitoring for all CAPA reports.

5.0 Computerized Systems

5.1 Policies / procedures

For requalification only:

If no changes have occurred since the last PRA QA qualification questionnaire, please check this box ☐

- Please provide the rationale if no changes applicable to the ENTIRE section:
- Otherwise please complete all questions in the table below and provide the requested attachments

Questions	Responses	
Are computerized systems used in any areas of operations? <i>If yes, please complete the rest of the section; if no please move to the next section</i>	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Is there an inventory of all computerized systems?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Is there a defined validation process for computerized systems / software?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Is there a change control procedure in place for computerized systems/software (e.g., installation of a new version of software)?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Provide a description of the system validation/system life cycle process, including change control procedures. A product approved by Management or Technical staff will go through the Software Development Life Cycle (SDLC). Once developed, the product is verified by Quality Control and validated by Quality Assurance prior to		

production release. Any changes to the released product will go through the Software Ongoing Maintenance Process.		
Is there a procedure describing the management of access rights?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Please provide the SOPs / written procedures for system validation/system life cycle process, including change control procedures; and access management (SOP IT 001: Cogstate IT Support for Software, Hardware, or Internal Systems Issues, SOP IT 002: Design and Development Process, SOP IT 003: Security Controls, SOP IT 011: Software Ongoing Maintenance Process, SOP IT 012: Software Testing Process, SOP IT 013: Maintenance and Control of the IT Infrastructure)		
Does your company have a written IT disaster/contingency plan in place in the event of an emergency or technical issue?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Please provide the latest IT disaster/contingency plan and the most recent test of this plan, if applicable? (Business Continuity and Disaster Recovery Plan)		

5.2 Computerized Systems Controls

For requalification only:		
If no changes have occurred since the last PRA QA qualification questionnaire, please check this box <input type="checkbox"/>		
<ul style="list-style-type: none"> Please provide the rational if no changes applicable to the ENTIRE section: Otherwise please complete all questions in the table below and provide the requested attachments 		
Questions	Responses	
Where does the company maintain computerized systems/software/regulatory data? (mark all that apply)	<input type="checkbox"/> Company Servers <input checked="" type="checkbox"/> Third Party Servers <input type="checkbox"/> On-Site Servers <input type="checkbox"/> Off-Site Servers	
Briefly describe the logical security to your company's data: Cogstate's infrastructure utilizes Active Directory and all Cogstate laptops are part of a single domain. The Cogstate network is protected by firewalls, monitored, and alerted for possible security attacks.		
Briefly describe the logical security to PRA's data, if applicable: Cogstate utilizes Microsoft Azure, which is part of its own network in the cloud protected by virtual firewalls and gateways to ensure secure transfer and protection of data.		
Is there a process in place to back-up critical computerized system information, software and data?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
If YES to the question above, indicate by which means data back-up is performed (choose all that apply)	<input type="checkbox"/> Server-based <input type="checkbox"/> Tape-based <input type="checkbox"/> Back-up data is offsite <input checked="" type="checkbox"/> Back-up data is at a third party	
Briefly describe the process of data back-ups, including frequency and method (e.g. incremental, full, etc.): Full daily back-ups are performed.		
Has the back-up system been tested to show effectiveness?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, please complete the following questions		
What is the frequency of testing (e.g., how often)	Annually	
When was it last tested (provide the date)	July 2018	
Was it documented?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No

Please provide the **SOPs / written procedures** related to data back-up as well as the documentation of the most recent test, if applicable
(SOP IT 009: Backup and Restore. Cogstate does not share back-up system test documentation externally)

Is there physical security on the computer system server room?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Is there automated computer anti-virus / anti-malware security?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	
Is your computer systems' audit trail in compliance with ALCOA (Attributable, Legible, Contemporaneous, Original, Accurate) principles	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Has the company:			
• Any plans to change the platform and/or computer systems (including relocation of servers)?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A
• Changed the version of your hardware platforms or computer systems within the last 12-18 months?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A
• Changed any supporting computerized systems / software e.g. bug tracking software within the last 12-18 months?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A
• Changed any underlying ancillary systems within the last 12-18 months?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Is there a procedure describing the handling of help desk requests?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

5.3 Computerized Systems providing product or service to customer

For requalification only:

If no changes have occurred since the last PRA QA qualification questionnaire, please check this box ☐

- Please provide the rational if no changes applicable to the ENTIRE section:
- Otherwise please complete all questions in the table below and provide the requested attachments

Questions	Responses	
Provide a list and brief description of the computerized systems in use that would be applicable for PRA contracted services to include: - <ul style="list-style-type: none"> The regulatory data they create, modify, maintain, archive, retrieve and transfer, if applicable: 21 CFR Part 11 risk assessment status, if applicable. Type of system (e.g. self-developed, off-the shelf, significantly re-configured third party software) The Cogstate Platform utilizes web-based cognitive tests launched from tablets or laptops at the clinical sites. Once completed, the tests upload their raw data to a centralized hub to be scored and routed to an off-the-shelf EDC system. There the data can be reviewed, cleaned, and eventually exported to the customer.		
Does your company design and develop computerized systems/software? (e.g. a GAMP (Good Automated Manufacturing Practice) 5 Category 5 system))	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Does your company use off-the-shelf systems for which only configuration within the original design has occurred? (e.g. GAMP 5 Category 3 system)	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Does your company significantly configure or re-program third party computerized systems /software after purchase? (e.g. GAMP 5 Category 4/5)	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

6.0 Quality Assurance Program

For requalification only:

If no changes have occurred since the last PRA QA qualification questionnaire, please check this box ☐

- Please provide the rational if no changes applicable to the ENTIRE section:
- Otherwise please complete all questions in the table below and provide the requested attachments

Questions	Responses
Is there a Quality Assurance department?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Are QA staff fully independent from operations?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Indicate the types of audits performed (check all that apply)	<input checked="" type="checkbox"/> Supplier / Vendor <input checked="" type="checkbox"/> In Process <input type="checkbox"/> Data/Report <input checked="" type="checkbox"/> Training Files <input checked="" type="checkbox"/> Project Files <input type="checkbox"/> Protocol <input type="checkbox"/> Other: _____
Please provide a copy of the internal audit schedule for the current year	
Are internal audit findings trended?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Is Management informed of internal audit findings?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Is a process in place to assess and re-assess vendors/sub- contractors?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Please provide the SOPs / written procedures related to internal and vendor/supplier audits (SOP ADM 006: Vendor Evaluation, SOP ADM 007: Audits)	

7.0 Service Category Specialty Table and Questions - Training

For requalification only:

If no changes have occurred since the last PRA QA qualification questionnaire, please check this box ☐

- Please provide the rational if no changes applicable to the ENTIRE section:
- Otherwise please complete all questions in the table below and provide the requested attachments

Questions	Responses
Is there a controlled process for screening and hiring trainers?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<p>If YES, please provide details:</p> <p>After a new position opens, the hiring manager and HR department review the list of candidates in the company's applicant tracking system. Following the initial review, candidates are selected for phone screens with a member of the HR department. HR will collect feedback and make recommendations to the hiring manager for the next round of interviews. The next round is a phone interview with the hiring manager. Following the phone interviews, the hiring manager will determine who should advance to the next round for an in-person interview. Once the finalist is selected, references are checked and paperwork is completed for final approval before moving forward with an offer.</p> <p>If Local Expert Advisors (LEADs) are required for rater training/certification purposes, the Clinician Network Manager will recruit/contract any additional resources by searching the existing LEADs network by reviewing the LEADs database, responses to LEAD Network Questionnaire, and submitted CVs to check if they meet the minimum requirements for the project. If Cogstate's existing LEADs network yield no viable candidates, the Clinician Network Manager will initiate recruitment using the LEAD Network Questionnaire and LEAD Recruitment Guidelines.</p>	

Do you have an internal procedure to define the raters training program?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
If YES, please provide written SOPs/procedures (SOP PRO 009: Rater Training)		
Do you create raters training program material?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
If YES, have employees creating content material a scientific/medical background?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
If YES, please provide anonymized CVs of key personnel		
If NO, please explain who is responsible for training program content creation		
Is the training program material to be reviewed by the client?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Who is responsible for approving training program content? The Cogstate Science Lead/Consultant assigned to a particular study.		
Is training effectiveness assessed?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
<p>If YES, please describe the process to assess training effectiveness</p> <p>Cogstate is contracted to provide monitoring services for many trials, which also serves to ensure raters are administering the scales as trained. If errors are observed, remediation may be required, as detailed below.</p> <p>If scoped for a particular study, candidate scale raters will be required to complete a practice administration of the test to a mock subject (which may be audio recorded). A Cogstate Local Expert Advisor (LEAD), who is a psychologist or neuropsychologist with expertise in the administration and scoring of the test, will review the submitted practice source documents (and audio recording, as necessary) to confirm that each rater has mastered the administration and scoring procedures.</p>		
Is a refresher training program in place?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
<p>If YES, how often is it planned?</p> <p>Refresher training is study-specific and can occur at any interval, if scoped at all. Refresher training is often planned annually or at the study mid-point (dependent on protocol variables and other services included such as central monitoring/data monitoring).</p> <p>While refresher training is protocol specific, it could involve quizzes, group web conferencing, practice administrations, watching videos and scoring against the gold-standard, applied training, etc.</p>		
Is rater training material prepared in English only?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Do you provide training material translation services?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
If YES, are your translators qualified?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Please provide anonymized CVs of appointed personnel (Cogstate uses certified third-party translation vendor services. A sample of CVs for our third-party vendor personnel has been provided with this submission)		
Do you create training material containing confidential information (e.g. Clinical Study Protocol, Sponsor name)?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
<p>If YES, how do you ensure confidentiality of data is maintained?</p> <p>All data is managed in accordance with all client agreements for confidentiality and all personal information is managed in accordance with GDPR.</p>		

8.0 Signatures

Have the Responsible Person sign below indicating that all provided information is accurate as of the date of the assessment and to indicate your agreement and understanding of the above listed Purpose and Use. Once signed, provide either a scanned version via email or a hard copy via mail.

Name of Responsible Person/Title:	<Print Name of Responsible Person/Title>
Signature of Responsible Person/Date:	<Insert Signature of Responsible Person/Date>

(Note: Electronic Signatures should only be used if all parties have the ability to eSign.)

9.0 Attachments

SOPs and Policies

(Please note all SOPs and policies listed below can be accessed in read-only online room via the link below:

<https://cogstate.box.com/s/19qdhlkbvha1pzw8fdsinrfhu20tn54v>)

SOP ADM 002: Training and Development
SOP ADM 006: Vendor Evaluation
SOP ADM 007: Audits
SOP ADM 008 CAPA, Deviations and Non-conformances
SOP HIP 01: HIPAA & GDPR Compliance
SOP HIP 02: Cogstate Information Security Program
SOP HIP 03: Acceptable Uses and Disclosures PHI & Processing of Personal Data
SOP HIP 04: Patient Access PHI and Data Subject Rights
SOP HIP 06: Acceptable Use Policy
SOP HIP 07: Facility Access Policy
SOP HIP 08: Information Systems Risk Management Policy
SOP HIP 09: Network System Security Measures
SOP HIP 10: Security Incident Response Plan
SOP HIP 11: Sanctions Enforcement Policy
SOP HIP 12: Identification Authentication
SOP HIP 13: Encryption Policy
SOP IT 001: Cogstate IT Support for Software, Hardware, or Internal Systems Issues
SOP IT 002: Design and Development Process
SOP IT 003: Security Controls
SOP IT 009: Backup and Restore
SOP IT 011: Software Ongoing Maintenance Process

SOP IT 012: Software Testing Process
SOP IT 013: Maintenance and Control of the IT Infrastructure
SOP PRO 001: Project Management
SOP PRO 009: Rater Training
SOP PRO 011: Lead Management SOP
SOP QM 001: Quality Management System Overview
Business Continuity and Disaster Recovery Plan
Code of Conduct_May 2018
Cogstate Employee Handbook (AUS) June 2018
Cogstate Employee Handbook (UK) June 2018
Cogstate Employee Handbook (US) June 2018
Cogstate SOP List_11Jun2019

Anonymized CVs

Cogstate Employee CV 1
Cogstate Employee CV 2
Cogstate Employee CV 3
Cogstate Employee CV 4
Cogstate Employee CV 5
Cogstate Employee CV 6

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